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10/638,173	08/06/2003	Robert Kain	ILLINC.026C1	3813
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KNOBBE MARTENS OLSON & BEAR LLP			FORMAN, BETTY J	
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IRVINE, CA 92614			1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/638,173

Applicant(s)

KAIN ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 60-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 25 July 2006 in which a Terminal Disclaimer was submitted, claims 27-59 were canceled and claims 60-93 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 25 April 2006, not reiterated below, are withdrawn in view of the amendments and Terminal Disclaimer. Applicant's arguments have been thoroughly reviewed, but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 60-93 are under prosecution.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 60-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Preliminary Amendment submitted 29 April 2004 added new claims 27-59. The new claims define the partitions separating the assay locations as "a non-permanent sealant",

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rubber, silicon, petroleum jelly, wax and parafilm". The specification (page 10, first full paragraph) defines the partitions as gaskets e.g. rubber or silicon. The specification further describes non-permanent sealants surrounding the periphery of the chamber to include rubber, silicon, petroleum jelly, wax and parafilm (page 21, lines 16-24). However, this passage is describing the periphery of the chamber and not the partitions between assay locations as newly recited in independent Claims 60, 71 and 83. While the specification describes assay location partitions as gaskets, rubber and silicon (page 10), the originally filed specification does not provide support for the partitions as instantly claimed.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 60-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al (U.S. Patent No. 6,232,066 filed 2 July 1998) in view of Walt et al (U.S. Patent No. 6,023,540, filed 14 march 1997).

Regarding Claim 60, Felder et al disclose a composition comprising substrate comprising a surface having first and second assay locations wherein the assay location have discrete sites comprising microspheres with bioactive agents (wells or dimples, Column 6, lines 38-51) and wherein the locations are separated by a partition comprising a non-permanent sealant (Column 5, lines 38-42). (i.e. physical barrier, Column 5, lines 19-28) wherein the microspheres are randomly distributed (Column 8, lines 39-42). Felder et al further teach the composition wherein the substrate comprises a plurality of depressions (e.g. dimples Column 6, lines 38-51) but they are silent regarding the dimples being configured to contain a single microsphere. However, microsphere-configured depressions were well known the in art at the time the claimed invention was made as taught by Walt et al.

Walt et al teach a similar composition comprising first and second subpopulations of microspheres randomly distributed on an array of wells (depressions) wherein the wells are configured to contain a single microsphere (Column 12, lines 42-45). Walt et al further teach that the configuration important for ensuring that light from each microsphere and reactions occurring on the microsphere are individually detected (Column 11, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the substrate configuration of Walt et al to the dimpled substrate of Felder et al. One of ordinary skill in the art would have been motivated to do so based on the importance taught by Walt and for the expected benefit of ensuring detection of individual microsphere and reactions occurring on the microsphere as taught by Walt et al (Column 11, lines 59-67).

Regarding Claim 61, Walt et al illustrate the substrate wherein substantially all the depressions include a microsphere (Fig. 7B).

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Regarding Claims 62-63, Felder et al disclose the substrate is transparent for optical detection (Column 5, lines 5-10) but does not specifically teach an optical fiber. However, Walt et al teach the similar device wherein the substrate is preferable an optical fiber whereby microsphere are optically coupled to the detector (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the optical fiber of Walt et al to the device of Felder et al for the expected benefit of one-to-one detection of individual microspheres and subpopulations via optical fiber and bundles as taught by Walt et al (Column 11, line 59-Column 12, line 15).

Regarding Claim 64, Felder et al disclose the composition wherein the non-permanent sealant is silicon or wax (Column 5, lines 38-42).

Regarding Claim 65, Felder et al disclose the composition wherein the substrate comprises an overlaying structure (e.g. piece of plastic) to define and fluidly insulate the assay regions (Column 5, lines 33-35). This overlaying plastic structure is reasonably interpreted as a gasket

Regarding Claim 66, Felder et al disclose the composition wherein the bioactive agent is DNA (Column 4, lines 34-62).

Regarding Claim 67, Felder et al disclose the composition wherein the substrate comprises a microscope slide (Column 5, line 2).

Regarding Claim 68, Felder et al disclose the composition wherein the substrate is with a hybridization chamber (i.e. the plate is covered for hybridization, Column 33, lines 49-52)

Regarding Claim 69, Felder et al disclose the composition wherein the substrate is a flexible membrane (i.e. nylon or nitrocellulose, Column 5, lines 3-4).

Regarding Claim 70, Felder et al disclose the composition wherein the first and second assay locations are separately enclosed (i.e. the partitioned regions are covered, Column 5, lines 19-45 and Column 33, lines 49-52).

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Regarding Claim 71 Felder et al disclose a method of making a composition comprising substrate comprising providing a surface forming a plurality of a plurality of depressions (e.g. dimples Column 6, lines 38-51) to provide first and second assay locations wherein the assay location have discrete sites comprising microspheres with bioactive agents (wells or dimples, Column 6, lines 38-51) and wherein the locations are separated by a partition comprising a non-permanent sealant (Column 5, lines 38-42). (i.e. physical barrier, Column 5, lines 19-28) randomly distributing the microspheres (Column 8, lines 39-42).

Felder et al teach the method wherein the substrate comprises a plurality of depressions (e.g. dimples Column 6, lines 38-51) but they are silent regarding the dimples being configured to contain a single microsphere. However, microsphere-configured depressions were well known the in art at the time the claimed invention was made as taught by Walt et al.

Walt et al teach a similar method comprising first and second subpopulations of microspheres randomly distributed on an array of wells (depressions) wherein the wells are configured to contain a single microsphere (Column 12, lines 42-45). Walt et al further teach that the configuration important for ensuring that light from each microsphere and reactions occurring on the microsphere are individually detected (Column 11, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the substrate configuration of Walt et al to the dimpled substrate of Felder et al. One of ordinary skill in the art would have been motivated to do so based on the importance taught by Walt and for the expected benefit of ensuring detection of individual microsphere and reactions occurring on the microsphere as taught by Walt et al (Column 11, lines 59-67).

Regarding Claim 72, Walt et al illustrate the substrate wherein substantially all the depressions include a microsphere (Fig. 7B).

Regarding Claims 73-74, Felder et al disclose the substrate is transparent for optical detection (Column 5, lines 5-10) but does not specifically teach an optical fiber. However, Walt

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et al teach the similar device wherein the substrate is preferable an optical fiber whereby microsphere are optically coupled to the detector (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the optical fiber of Walt et al to the device of Felder et al for the expected benefit of one-to-one detection of individual microspheres and subpopulations via optical fiber and bundles as taught by Walt et al (Column 11, line 59-Column 12, line 15).

Regarding Claim 75, Felder et al disclose the composition wherein the non-permanent sealant is silicon or wax (Column 5, line s38-42).

Regarding Claim 76, Felder et al disclose the composition wherein the substrate comprises an overlaying structure (e.g. piece of plastic) to define and fluidly insulate the assay regions (Column 5, lines 33-35). This overlaying plastic structure is reasonably interpreted as a gasket

Regarding Claim 77, Felder et al disclose the composition wherein the bioactive agent is DNA (Column 4, lines 34-62).

Regarding Claim 78, Felder et al disclose the composition wherein the substrate comprises a microscope slide (Column 5, line 2).

Regarding Claim 79, Felder et al disclose the composition wherein the substrate is with a hybridization chamber (i.e. the plate is covered for hybridization, Column 33, lines 49-52)

Regarding Claim 80, Felder et al disclose the composition wherein the substrate is a flexible membrane (i.e. nylon or nitrocellulose , Column 5, lines 3-4).

Regarding Claim 81, Felder et al disclose the composition wherein the first and second assay locations are separately enclosed (i.e. the partitioned regions are covered, Column 5, lines 19-45 and Column 33, lines 49-52).

Regarding Claim 82, Felder et al the substrate is etched to provide wells (Column 5, lines 28-30) and Walt et al define the etched depressions as wells (Abstract).



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Regarding Claim 83, Felder et al disclose a composition comprising substrate comprising a surface having depressions thereon (Column 5, lines 28-30) and first and second assay locations wherein the assay location have discrete sites comprising microspheres with bioactive agents (Column 6, lines 38-51) and wherein the locations are separated by a partition comprising a non-permanent sealant (Column 5, lines 19-28) wherein the microspheres are randomly distributed (Column 8, lines 39-42). Felder et al further teach the composition wherein the substrate comprises a plurality of depressions (e.g. dimples Column 6, lines 38-51) but they are silent regarding the dimples being configured to contain a single microsphere. However, microsphere-configured depressions were well known the in art at the time the claimed invention was made as taught by Walt et al.

Walt et al teach a similar composition comprising first and second subpopulations of microspheres randomly distributed on an array of wells (depressions) wherein the wells are configured to contain a single microsphere (Column 12, lines 42-45). Walt et al further teach that the configuration important for ensuring that light from each microsphere and reactions occurring on the microsphere are individually detected (Column 11, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the substrate configuration of Walt et al to the dimpled substrate of Felder et al. One of ordinary skill in the art would have been motivated to do so based on the importance taught by Walt and for the expected benefit of ensuring detection of individual microsphere and reactions occurring on the microsphere as taught by Walt et al (Column 11, lines 59-67).

Regarding Claim 841, Walt et al illustrate the substrate wherein substantially all the depressions include a microsphere (Fig. 7B).

Regarding Claims 85-86, Felder et al disclose the substrate is transparent for optical detection (Column 5, lines 5-10) but does not specifically teach an optical fiber. However, Walt et al teach the similar device wherein the substrate is preferable an optical fiber whereby microsphere are optically coupled to the detector (Abstract). It would have been obvious to one

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of ordinary skill in the art at the time the claimed invention was made to apply the optical fiber of Walt et al to the device of Felder et al for the expected benefit of one-to-one detection of individual microspheres and subpopulations via optical fiber and bundles as taught by Walt et al (Column 11, line 59-Column 12, line 15).

Regarding Claim 87, Felder et al disclose the composition wherein the non-permanent sealant is silicon or wax (Column 5, line s38-42).

Regarding Claim 88, Felder et al disclose the composition wherein the substrate comprises an overlaying structure (e.g. piece of plastic) to define and fluidly insulate the assay regions (Column 5, lines 33-35). This overlaying plastic structure is reasonably interpreted as a gasket

Regarding Claim 89, Felder et al disclose the composition wherein the bioactive agent is DNA (Column 4, lines 34-62).

Regarding Claim 90, Felder et al disclose the composition wherein the substrate comprises a microscope slide (Column 5, line 2).

Regarding Claim 91, Felder et al disclose the composition wherein the substrate is with a hybridization chamber (i.e. the plate is covered for hybridization, Column 33, lines 49-52)

Regarding Claim 92, Felder et al disclose the composition wherein the substrate is a flexible membrane (i.e. nylon or nitrocellulose , Column 5, lines 3-4).

Regarding Claim 93, Felder et al disclose the composition wherein the first and second assay locations are separately enclosed (i.e. the partitioned regions are covered, Column 5, lines 19-45 and Column 33, lines 49-52).

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double

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patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 60-93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-30 of U.S. Patent No. 6,429,027 in view of Felder et al (sup 6,232,066). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions comprising microsphere populations within assay locations. The claim sets differ in that the patent composition defines a number of microspheres per location. However, the open claim language "comprising" of the instant claims encompasses the additional elements of the patent composition. The claims sets further differ in that the instant claims define the substrate as having a nonpermanent sealant separating the assay regions. However, Felder et al teaches non-permanent sealants between assay regions wherein the sealants define and fluidically insulated the assay regions (Column 5, lines 30-45). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sealants of Felder et al to the '027 assay regions. One of ordinary skill in the art would have been motivated to do so for the expected benefit of defining and fluidically insulating the assay regions as desired in the art (Felder et al, Column 5, lines 30-45).

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8. Claims 60-93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,998,274 in view of Felder et al (sup 6,232,066). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions comprising microsphere populations within assay locations. The claim sets differ in that the patent composition defines a number of microspheres per location. However, the open claim language "comprising" of the instant claims encompasses the additional elements of the patent composition.

The claims sets further differ in that the instant claims define the substrate as having a nonpermanent sealant separating the assay regions. However, Felder et al teaches non-permanent sealants between assay regions wherein the sealants define and fluidically insulated the assay regions (Column 5, lines 30-45). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sealants of Felder et al to the '274 assay regions. One of ordinary skill in the art would have been motivated to do so for the expected benefit of defining and fluidically insulating the assay regions as desired in the art (Felder et al, Column 5, lines 30-45).

### **Conclusion**

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
September 11, 2006